

What is claimed is:

1. A method for diagnosis of bacterial  
exacerbations of chronic lung disease in an individual  
5 comprising the steps of:

a) obtaining a sputum sample from the  
individual, wherein the sputum sample comprises lower  
respiratory tract secretions;

b) determining the level of elastase in the  
10 sputum sample; and

c) comparing the level of elastase in the sputum  
sample to a reference standard, wherein an increase in the  
elastase level over the reference standard is indicative  
of bacterial induced exacerbations of chronic lung  
15 disease.

2. The method of claim 1, wherein the elastase level  
is determined by contacting the sputum sample with a  
chromogenic substrate of elastase.  
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3. The method of claim 2, wherein the chromogenic  
substrate for elastase activity is N-methoxysuccinyl-ala-  
ala-pro-val-p-nitroanilide.

4. The method of claim 1, wherein the bacterial  
exacerbation is induced by bacteria selected from the  
group consisting of H. influenzae, M. catarrhalis, P.  
aeruginosa and S. pneumoniae.  
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5. The method of claim 4, wherein the bacteria is H.  
influenzae.  
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6. The method of claim 4, wherein the bacteria is M.  
catarrhalis.  
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7. The method of claim 4, wherein the bacteria is S.  
pneumoniae.

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8. The method of claim 4, wherein the bacteria is *P. aeruginosa*.

9. The method of claim 1, wherein the chronic lung  
5 disease is chronic bronchitis.

10. The method of claim 1, wherein the sputum sample  
is processed to remove cellular components prior to  
determination of elastase levels.  
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11. A method for diagnosis of bacterial  
exacerbations of chronic lung disease in an individual  
comprising the steps of:

a) obtaining a sputum sample from the  
15 individual, wherein the sputum sample comprises lower  
respiratory tract secretions; and

b) determining the presence or absence of  
elastase in the sputum sample by contacting the sample  
with an absorbent carrier coated with a chromogenic  
20 substrate therefor, wherein a change in color of the  
absorbent carrier is indicative of bacterial induced  
exacerbations of chronic lung disease.

12. The method of claim 11, wherein the chromogenic  
25 substrate for elastase activity is N-methoxysuccinyl-ala-  
ala-pro-val p-nitroanilide.  
✓

13. The method of claim 11, wherein the bacterial  
exacerbation is induced by bacteria selected from the  
group consisting of *H. influenzae*, *M. catarrhalis*, *P.*  
30 *aeruginosa* and *S. pneumoniae*.  
✓

14. The method of claim 13, wherein the bacteria is  
*H. influenzae*.  
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15. The method of claim 13, wherein the bacteria is  
*M. catarrhalis*.

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16. The method of claim 13, wherein the bacteria is *P. aeruginosa*.

17. The method of claim 13, wherein the bacteria is  
5 *S. pneumonia*.

18. The method of claim 11, wherein the sputum  
sample is processed to remove cellular components prior to  
determination of presence or absence of elastase.

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19. A method for diagnosis of *H. influenzae* induced  
exacerbations of chronic lung disease in an individual  
comprising the steps of:

a) obtaining a sputum sample from the  
15 individual, wherein the sputum sample comprises lower  
respiratory tract secretions;

b) determining the level of IL-8 in the sputum  
sample; and

c) comparing the level of IL-8 in the sputum to  
20 a reference standard, wherein an increase in the IL-8 over  
reference standard is indicative of *H. influenzae* induced  
exacerbations of chronic lung disease.

20. A method for diagnosis of *H. influenzae* or *M.*  
25 *catarrhalis* induced exacerbations of chronic lung disease  
in an individual comprising the steps of:

a) obtaining a sputum sample from the  
individual, wherein the sputum sample comprises lower  
respiratory tract secretions;

b) determining the level of TNF- $\alpha$  in the sputum  
30 sample; and

c) comparing the level of TNF- $\alpha$  in the sputum to  
a reference standard, wherein an increase in the TNF- $\alpha$   
over the reference standard is indicative of *H. influenzae*  
35 or *M. catarrhalis* induced exacerbations of chronic lung  
disease.

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